

## **Environmental Technology Verification**

### **Test/QA Plan for Biological and Aerosol Testing of General Ventilation Air Cleaners**

EPA Cooperative Agreement R-83191101  
Research Triangle Institute Project 09309

Prepared by:

Air Pollution Control Technology Center  
Research Triangle Institute  
Research Triangle Park, NC

Approved by:

APCT Center Director: Signed by Andrew Trenholm, August 21, 2006  
Andrew Trenholm

APCT Center Quality Manager: Signed by Cary Eaton, August 21, 2006  
W. Cary Eaton

EPA Project Officer: Signed by Michael Kosusko, August 30, 2006  
Michael Kosusko

EPA Quality Manager: Signed by Paul Groff, August 30, 2006  
Paul Groff

This document serves as the Test and Quality Assurance (QA) Plan for the verification of general ventilation air cleaners that reduce aerosols and bioaerosols. This document was developed under Cooperative Agreement R-83191101 between EPA and the Research Triangle Institute for implementation of the air pollution control technology center of the environmental technology verification program. The quality management plan under which this work is conducted is the *Quality Management Plan for Verification Testing of Air Pollution Control Technology*, Revision 2.2, June 2005.

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### **A3: Distribution List**

#### EPA

Mr. Michael Kosusko

Mr. Paul Groff

#### Research Triangle Institute

Mr. Clint Clayton

Dr. W. Cary Eaton

Ms. Karin Foarde

Ms. Deborah Franke

Mr. Michael Herman

Mr. James Hanley

Ms. Kathleen Owen

Ms. Lauren Pugh

Dr. C. E. Tatsch

Mr. Andrew Trenholm

Ms. Tricia Webber

## List of Acronyms/Abbreviations/Definitions

ADQs	audits of data quality
AGI	all glass impinger
ANSI	American National Standards Institute
ASHRAE	American Society of Heating, Refrigerating, and Air-conditioning Engineers
ASME	American Society of Mechanical Engineers
cm <sup>3</sup>	cubic centimeter(s)
CFU	colony forming unit
cfm	cubic feet per minute
cm	centimeter(s)
CPC	condensation particle counter
culturable	able to be grown on microbiological media
CV	coefficient of variance
d <sub>50</sub>	50% cut point on Andersen sampler
DQO	data quality objective
E <sub>1</sub> , E <sub>2</sub> , E <sub>3</sub>	average minimum particle-size efficiency designator of ASHRAE 52.2
electret	a filter comprised of fibers that contain an embedded electrostatic charge
EPA	U.S. Environmental Protection Agency
Eq.	equation
ETV	Environmental Technology Verification Program
g	gram(s)
HEPA	high efficiency particulate air
in.	inch(es)
ISO	International Organization for Standardization
KCl	potassium chloride
Kr	Krypton
L	liter(s)
m <sup>3</sup>	cubic meter(s)
MERV	minimum efficiency reporting value of ASHRAE 52.2
min	minimum
min.	minute(s)
ML	microbiology laboratory
m	meter(s)
mL	milliliter(s)
mm	millimeter(s)
MSDS	material safety data sheet
MS2	bacterial virus or bacteriophage

OPC	optical particle counter
PCO	photocatalytic oxidation
PEs	performance evaluations
PFU	plaque forming unit
PSE	particle size (removal) efficiency
psig	pounds per square inch gauge
PSL	polystyrene-latex
QA	quality assurance
QC	quality control
QM	quality manager
QMP	quality management plan
RH	relative humidity
RTI	Research Triangle Institute
sec	second(s)
SMPS	scanning mobility particle counter
SOP	standard operating procedure
t	temperature
T/QAP	test/quality assurance plan
TSAs	technical system audits
$\mu\text{m}$	micrometer



## **SECTION A: PROJECT MANAGEMENT**

### **A4: Project/Task Organization**

The U.S. Environmental Protection Agency (EPA) established the Environmental Technology Verification Program (ETV) to accelerate the development and commercialization of improved environmental technology through third party verification and reporting of performance. Under a cooperative agreement with EPA, Research Triangle Institute (RTI) operates the Air Pollution Control Technology Center (APCT). RTI will verify the filtration efficiency and bioaerosol inactivation efficiency of heating, ventilation and air conditioning (HVAC) air cleaners for culturable bioaerosol and aerosol challenges. RTI will perform the testing, evaluate the data, and prepare the verification reports and the verification statements.

The scope of this test/quality assurance (QA) plan (T/QAP) covers in-duct air cleaners based on filtration, ultraviolet (UV) illumination, photocatalytic oxidation (PCO) and combinations of those technologies, however the focus is on filters. The T/QAP with addendum for specific technology can be used for UV, PCO and other technologies if they are compatible with the test facilities and procedures of the T/QAP. It is anticipated that the devices tested will be compatible with a nominal 24" x 24" test duct cross section.

This T/QAP is based on previous work for three ETV-related projects. Stakeholder groups were convened under these projects to provide input into the selection of technologies and into the development of protocols and T/QAPs.

- Under the ETV Indoor Air Pilot, a test protocol<sup>1</sup> and test plan<sup>2</sup> were developed and validated for general ventilation media devices.
- As part of the ETV Safe Buildings for homeland security, a test protocol<sup>3</sup> and test plan<sup>4</sup> developed which included bioaerosol testing.
- Recently, the EPA Technology Testing and Evaluation Program (TTEP) developed a test method for testing UV light systems used in ventilation ducts for bioaerosols<sup>5</sup>.

The methods and procedures in these documents were supplemented based on RTI's experience conducting testing for commercial clients for bioaerosols and testing based on American National Standards Institute (ANSI)/American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. (ASHRAE) Standard 52.2-1999<sup>6</sup>, *Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size* (ASHRAE 52.2-1999).

The various QA and management responsibilities are divided between EPA and RTI key project personnel as defined below. The lines of authority between key personnel for this project are shown on the project organization chart in Figure 1.

#### **A4.1: Management Responsibilities**

Project management responsibilities are divided among the EPA and RTI personnel as listed below.

##### **A4.1.1: EPA Project Officer**

The EPA center project officer (EPA PO), Mr. Michael Kosusko, monitors and guides the progress of the APCT Center. The EPA PO has overall EPA ETV Program responsibility for the quality of verification tests conducted by the center. The EPA PO is responsible for coordinating

EPA QA and technical peer reviews and EPA approval of generic verification protocol (GVP) revisions, test/QA plans (T/QAPs), and verification reports and statements. The EPA PO recommends the resources necessary to meet project objectives and requirements.

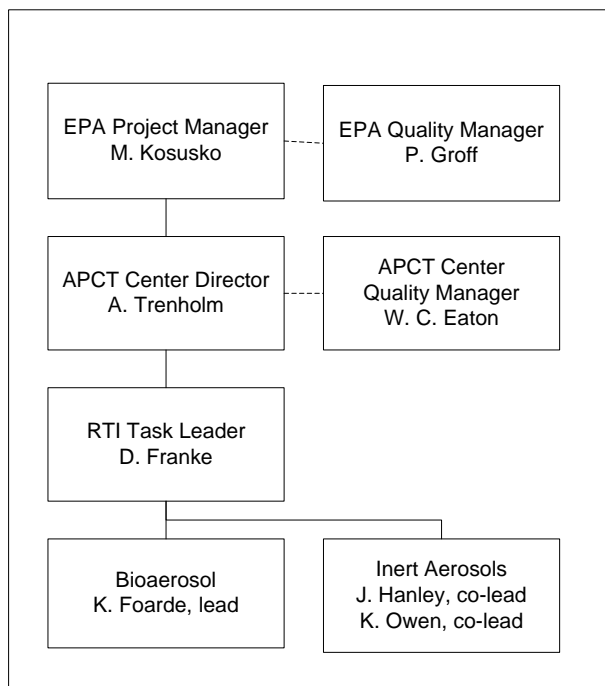


Figure 1. Organization chart. Dotted lines indicate organizational independence.

#### **A4.1.2: APCT Center Director**

The APCT Center director, Mr. Andrew Trenholm, has overall responsibility for APCT Center activities, which includes oversight of all verification test planning, execution, and reporting. The director maintains communication with EPA to assure mutual understanding and conformance with EPA quality procedures and expectations and ETV policies and procedures, develops T/QAPs in cooperation with technology developer/vendors, ensures that all subcontractors [i.e., testing organizations (TOs)] and analytical labs conform to the requirements of this GVP and resulting T/QAPs, and reviews and approves internal QA reviews and assessment reports and initiates corrective actions. The director also develops agreements for verification tests with technology developers/vendors and other collaborators, including cost-sharing agreements, monitors and directs each test's task leader, directs subcontractor efforts, and coordinates with the EPA PO. The director oversees preparation and internal review and approvals of GVP revisions, T/QAPs, and verification reports and statements. The director submits these documents to the EPA PO for review and approval.

#### **A4.1.3: RTI Task Leader**

The RTI task leader, Deborah Franke has responsibility for the task, including defining task objectives and developing a detailed work plan schedule. She will work with vendors and stakeholders, review work progress to ensure that task budgets and schedules are met, and prepare verification reports and verification statements.

Ms. Karin Foarde, the bioaerosol technical lead, will have responsibility for the technical oversight required for the bioaerosol testing. She will be assisted by Tricia Webber, Microbiology Laboratories Supervisor. James Hanley and MKathleen Owen will be co-technical leads for the inert aerosol tests. These technical leaders will review the results for consistency based on their experience with the respective components of the tests.

The technical leaders will assist the RTI task leader with the work plan schedule, review/prepare operating procedures applicable to the testing and review test apparatus and procedures prior to commencement of testing. They will oversee testing of the ventilation devices, review test data /results for attainment of DQOs and reasonableness, and submit test results to RTI task leader. If needed they will initiate corrective actions.

#### **A4.2: Quality Assurance Responsibilities**

QA responsibilities are divided among the EPA personnel and RTI personnel as listed below.

##### **A4.2.1: EPA Quality Manager**

The EPA quality manager (EPA QM), Mr. Paul Groff, communicates ETV quality system requirements, quality procedures, and quality issues to the EPA PO and APCT Center director and quality manager. He reviews and approves GVP revisions, T/QAPs, verification reports and statements, and QA reports prepared by the center, including QA evaluations and audits. He performs independent technical systems audits (TSAs) and performance evaluation audits (PEAs) of verification tests, as appropriate, to verify conformance to the quality requirements of the applicable T/QAP. He provides assistance to APCT Center personnel in resolving QA issues.

##### **A4.2.2: APCT Center Quality Manager**

- The APCT Center quality manager (QM), Dr. W. Cary Eaton, assists the director in revisions of this GVP and preparation of subsequent T/QAPs. The QM is free from personal and external barriers to independence, is organizationally independent from data collection activities, and is able to maintain an independent attitude and appearance. The QM is responsible for ensuring that QA/quality control (QC) procedures described in this GVP are followed. The QM communicates directly with the EPA QM and with TO-QMs on quality-related issues, providing technical assistance to TOs regarding EPA quality requirements. The QM prepares the QA section of each verification report. The QM reviews and approves T/QAPs, verification reports and statements, verification test results, and associated quality records. The QM communicates directly with TO-QMs on quality-related issues. The QM is also responsible for conducting independent assessments of the quality systems of TOs and independent technical assessments (i.e., technical systems audits [TSAs] and performance evaluation audits [PEAs]) of verification tests in cooperation with the EPA QM. The QM performs and documents audits of data quality (ADQs) on 10% of test data. The QM is responsible for determining and documenting the effectiveness of corrective actions implemented in response to independent assessment findings.

### **A5: Problem Definition/Background Information**

This ETV T/QAP for Biological and Aerosol Testing of General Ventilation Air Cleaners describes the test and QA procedures that will be used to provide data on the removal efficiency of bioaerosols and inert aerosols by general ventilation air cleaners.

While data and methods are available for measuring single-pass inert particle removal efficiencies of air cleaners and filters, no standard method exists for evaluating culturable bioaerosol reduction by these devices. RTI has developed a test method for measuring culturable bioaerosol filtration efficiencies of devices ranging from a room air cleaner to duct-mounted ventilation filters to vacuum cleaner filters<sup>7,8,9</sup>. Additionally, the method was used in a previous ETV project for Biological Testing of General Ventilation Filters (EPA Contract No. GS10F0283K-BPA-1; Task Order 1101. Research Triangle Institute Project 08787.001)<sup>4</sup>.

The methods discussed in the previous paragraph are the basis for the bioaerosol test and the sub-0.3  $\mu\text{m}$  inert particle tests in this T/QAP. Inert particle efficiency tests are used also as a point of comparison for QA/QC of the culturable bioaerosol results and will be used as a "self-consistency" check within the QA framework for the bioaerosol tests.

Under this T/QAP, the following tests may be performed:

1. A complete ASHRAE 52.2-1999 test.
2. Bioaerosol test with four culturable microorganisms.
3. Inert particle tests, using potassium chloride (KCl) aerosol:
  - a. 0.3 – 10  $\mu\text{m}$ , with optical particle counter (OPC) measurement,
  - b. 0.03 – 0.3  $\mu\text{m}$ , with scanning mobility particle counter (SMPS) measurement, and
  - c. 0.03 – 10  $\mu\text{m}$ , with combined SMPS and OPC measurements.

The above tests will be performed on clean, conditioned and dust-loaded devices as defined in this paragraph. For options 2 and 3, conditioning with the sub-micron aerosol and dust loading with ASHRAE dust will be required for all devices that incorporate filter media. Filter media is the fibrous material used in air filters and other air cleaners to remove particles via filtration. Examples include microglass and polypropylene fibers. Filter media is typically assembled in the form of a flat panel, pleated or bag configuration. The bioaerosol test includes inert testing, as applicable, for QA/QC and reporting purposes.

All of these tests will be performed in a fully qualified ASHRAE 52.2-1999 test duct. This test duct operates at positive pressure to minimize infiltration of room air or bioaerosol. The KCl aerosol used for the ASHRAE 52.2-1999 and other inert aerosol tests and the bioaerosols are injected upstream of a mixing baffle to provide aerosol mixing with the airstream. Bioaerosol and inert aerosol concentrations are measured both upstream and downstream of the test section where the air cleaner is installed to obtain the challenge and penetrating concentrations, respectively.

Both conditioning and dust loading are done so that the testing better represents what happens when filters are used in real life. Most media filters increase in efficiency as they are used and dust collects on the media. Electret filters have an electrostatic charge applied during manufacturing. These filters may decrease in efficiency at the start of their use cycle and,

possibly, throughout the use cycle if the filters are replaced before significant loading (dust accumulation) occurs. For ASHRAE 52.2-1999, the conditioning step (also called the first dustload) challenges the filter with ASHRAE dust (a mixture of carbon black, cotton linters, and Arizona road dust) until either a pressure drop increase of 10 Pa is achieved or 30 g of dust is fed, whichever one comes first. Relative to the 25%, 50%, 75% and 100% dust load steps used in the ASHRAE 52.2-1999 test, this is a very low dust challenge intended to simulate dust loading during the early states of the filter's use. The dust loading with ASHRAE dust is used to simulate the changes that can occur as a media filter accumulates dust; this usually results in an increase in efficiency, but can lead to an efficiency decrease if the filter sheds the dust instead of retaining it.

The recommended submicron conditioning step was recently developed as a way to more closely mimic the actual drop-off in efficiency as seen for electret media. Where the ASHRAE 52.2-1999 conditioning step may show a decrease in efficiency for these filters, it is usually much less than that shown in situ and is unlikely to show a drop-off for the larger particle sizes even though many media filters do drop-off in efficiency across the entire particle size range. Thus this step is needed to simulate real use efficiencies.

An addendum may be added to this test plan when testing UV, PCO or other devices to cover device-specific handling or additional measurements.

## **A6: Task Description and Schedule**

The task consists of the steps summarized below:

1. Procuring the general ventilation devices for testing from participating manufacturers,
2. Subjecting each air cleaner to the tests chosen by the manufacturer as listed in A5,
3. Preparing verification reports and statements.

### **A6.1: Task Description**

#### **A6.1.1: Identification and Acquisition of Devices**

Devices will be selected by the manufacturers and shipped to RTI. The full name and description of the product will also be provided. If a media device, a separate filter (or device) will be provided for each ASHRAE 52.2-1999 test; the bioaerosol tests and inert test may be performed on the same filter if desired. For devices with filters, each manufacturer should provide a backup filter to be used if, for example, the other filters are damaged in transit. Kathleen Owen will be the custodian of the devices and will be responsible for storage, labeling, etc. of the devices. For non-media devices, which tests are appropriate and how many units are needed will need to be determined on an individual basis in consultation between the manufacturer and the testing personnel.

#### **A6.1.2: Performance of ASHRAE 52.2-1999 Test**

The ASHRAE 52.2-1999 test will be performed per the standard and will establish the minimum efficiency reporting value (MERV) and other parameters as required in the standard. ASHRAE designed the MERV to represent a filter's minimum performance over multiple particle sizes. In general, a higher MERV indicates higher filter efficiency. Most commercial filters and high end residential filters are now marketed using the MERV. The filtration efficiencies (average of the minimum composite efficiency) are presented by particle size groupings: E1, 0.3 to 1.0  $\mu\text{m}$ ; E2,

1.0 to 3.0  $\mu\text{m}$ ; and E3, 3.0  $\mu\text{m}$  to 10  $\mu\text{m}$ . If other tests are performed on the same model of device, performing the ASHRAE 52.2-1999 test in RTI's laboratory will yield a consistent set of MERV, inert efficiency and bioaerosol efficiency measurements for a device type.

#### **A6.1.3: Performance of Culturable Bioaerosol Testing**

Biological testing will be performed using four different bioaerosols and one inert aerosol. If ASHRAE 52.2-1999 testing is also performed, a second device will be used for the bioaerosol testing if the device contains media. First, the initial efficiency will be determined using both the biological and the inert aerosols. The inert testing will cover the typical ASHRAE 52.2-1999 particle size range of 0.3-10  $\mu\text{m}$ . If the device contains media, the initial efficiencies will be followed by

- Submicrometer conditioning (if applicable, see A5) and the biological efficiency will be determined after conditioning,
- The device will then be loaded with ASHRAE test dust (if applicable, see A5) to obtain the final pressure drop as appropriate based on the MERV estimated by the inert particles or as chosen by the manufacturer. The bioaerosol efficiencies after dust-loading will be determined. Table 12-1 of the ASHRAE 52.2-1999 standard provides information on the minimum final resistance to be used for each MERV value.

The specifics of the testing will be discussed in further detail in Section B1.2.

The use of microorganisms as the challenge aerosol requires that a number of technical issues be addressed either in this document or in device-specific addenda. These issues include:

- Maintaining the survivability and culturability of the organisms through the aerosol generation and collection process,
- Determining whether the test organisms are being aerosolized as singlets (or single organisms) with a narrow size distribution,
- Generating the bioaerosol challenge in sufficient concentration to maintain the sampling duration within the sample time limits of the bioaerosol sampler,
- Establishing the generation protocol for the test organisms.

While all of these issues have been addressed in earlier RTI work, they will be readdressed as needed based on the specific organisms used and the technologies being tested. An addendum will be added to the test/QA plan for specific technologies to identify any variances from this plan.

#### **A6.1.4 Performance of Inert Particle Testing**

Inert testing will be performed using KCl aerosol on the device when (1) clean and, if applicable (see A5), (2) conditioned and (3) fully dust-loaded. The device is fully dust-loaded when the minimum final resistance is reached as specified in Table 12-1 of the standard. If ASHRAE 52.2-1999 testing is performed, a different device will be used for this testing if the device contains media. If the bioaerosol testing is performed, this testing may be interspersed with that testing. First, the initial efficiency will be determined using KCl generated by the ASHRAE 52.2 method and by a Collison nebulizer. The standard generation method will be used with testing with the OPC covering 0.3-10  $\mu\text{m}$ ; the nebulizer will be used with the SMPS to cover the particle size range of 0.03-0.3  $\mu\text{m}$ . If applicable (see A5), the initial efficiencies will be followed by:

- Submicrometer conditioning with the inert efficiency to be determined after conditioning and between conditioning steps,
- The device will be loaded with ASHRAE test dust to obtain the final pressure drop as appropriate based on the MERV estimated by the inert particles (Table 12-1 of the standard) or as chosen by the manufacturer; the inert efficiencies after dust-loading will be determined.

The specifics of the testing will be discussed in further detail in Section B1.1.

#### A6.1.5: Preparation of Report

The final step is to complete the verification report and verification statement for each product and test performed and submit them to the EPA.

#### A6.2: Schedule

If multiple products of a given type are submitted for verification, the products could be run as a batch and the report for each product issued at the same time. It is expected that in general products will be tested individually and the report issued when approved by EPA.

#### A7: Data Quality Objectives and Criteria for Measurement Data

Data quality objectives (DQOs) are qualitative and quantitative statements designed to ensure that the type, quality, and quantity of data used are appropriate for the intended application. The DQOs for the critical measurements are found in Tables 1 and 2. The test specifications are found in Appendix A.

**Table 1. DQOs for Inert Aerosol Tests**

Parameter	Frequency and description	DQO
OPC (optical particle counter): Penetration error limit for OPC data	Each test. Statistical check of data quality. Expected to be achieved on tests of clean air cleaners. May not always be achieved with dust-loaded air cleaners if the air cleaner sheds a significant amount of the collected dust.	<p>Per definitions and procedures of ASHRAE 52.2 Section 10.6.4<sup>6</sup></p> $\sigma \frac{\tau}{\sqrt{n}} \leq 0.07 P \text{ or } 0.05 \text{ whichever is greater for } 0.3 - 3 \mu\text{m}$ $\sigma \frac{\tau}{\sqrt{n}} \leq 0.15 P \text{ or } 0.05 \text{ whichever is greater for } 3 - 5.5 \mu\text{m}$ $\sigma \frac{\tau}{\sqrt{n}} \leq 0.20 P \text{ or } 0.05 \text{ whichever is greater for } 5.5 - 10 \mu\text{m}$ <p><math>\tau</math> = T-distribution variable, <math>n</math> = number of samples,  <math>P</math> = penetration (fraction), <math>\sigma</math> = standard deviation</p>

**Table 2. DQOs for Filtration Efficiency for Culturable Bioaerosol**

Parameter	Frequency and description	Control Limits	
Minimum upstream counts for samplers	Each efficiency test.	Minimum of 10 CFU <sup>a</sup> /plate or PFU <sup>b</sup> /plate	
Maximum counts for samplers	Each efficiency test.	Maximum of 500 CFU/plate or 800 PFU <sup>b</sup> /plate	
100% Penetration (correlation test)	Performed at least once per test sequence per organism.	Test Organism	Acceptable Penetration Range
		<i>B. atrophaeus</i>	0.85 to 1.15
		<i>S. marcescens</i>	0.80 to 1.20
		MS2	0.75 to 1.25
Upstream CFUs	Each test. Statistical check of data quality.	CV <sup>c</sup> ≤ 0.25	
Upstream PFUs	Each test. Statistical check of data quality.	CV <sup>c</sup> ≤ 0.35	

<sup>a</sup> CFU = colony forming units

<sup>b</sup> PFU = plaque forming unit

<sup>c</sup> CV = coefficient of variance

All data will be reviewed for accuracy (correctness) and reasonableness. If the results are deemed unreasonable by the technical leaders (e.g., internally inconsistent), they will be discarded, the procedures reviewed, and the test repeated if necessary. Occasional data points within a test are obvious outliers and will be discarded based on the statistical tests described in and/or referenced by ASTM Standard Practice E 178-02, Standard Practice for Dealing with Outlying Observations<sup>10</sup> without requiring the entire test to be repeated. While exact agreement is not expected (due to the different measurements devices) similar results are expected.

#### **A8: Special Training Requirements/Certification**

There are no specialized certification requirements specified for these tests. The RTI technical leads will be responsible for overseeing all work and ensuring that all personnel are fully trained in each operation and procedure for the testing.

The method chosen for analysis of the inert aerosol particle size efficiency of ventilation devices in the laboratory is restricted to use by, or under the supervision of, personnel experienced in the use of an OPC and skilled in the interpretation of raw count data.

In addition, for the bioaerosol tests, all of RTI's Microbiology Department staff will have completed at least one formal microbiology course (college or professional/society sanctioned) and gone through extensive informal laboratory training in the microbiology techniques needed for this task.

#### **A9: Documentation and Records**

This section identifies the documents and reports to be generated as part of the verification program and the information to be included in the verification reports and verification statements. A description of the data management system established for this task is presented in Section B10.



Requirements for record keeping and data management for the overall program are found in the U.S. EPA, Environmental Technology Verification Program Quality Management Plan<sup>11</sup>. All SOPs are maintained on file at RTI. Access to these files is permitted on-site at RTI.

## **A9.1: Laboratory Documentation**

### **A9.1.1: ASHRAE 52.2-1999 and Inert Aerosol Tests**

The test operator for the inert aerosol test will record the test data and run notes on test run sheets prepared specifically for these tests (An example is presented in Appendix B.) The sheets will be kept in a labeled three-ring binder. The run sheets are designed to prompt the test operator for all required test information:

- Testing date, time, and operator;
- Manufacturer and model number of device;
- Physical description of the device;
- QA checks on the equipment and data; and
- Test conditions (temperature, relative humidity, atmospheric pressure, air flow rate, device pressure drop).

The particle count data generated by the OPC are recorded by the computer. The file will be saved to the hard drive and later copied to a floppy disk or shared directory for backup.

### **A9.1.2: Bioaerosol Tests**

The bioaerosol test operator will record the test data and notes on a bioaerosol test run sheet (presented in Appendix C). The sheets are kept in a labeled three-ring binder. The run sheets are patterned from the inert aerosol run sheets and designed to prompt the test operator for all required test information:

- Device and run number;
- Testing date and operator;
- Test conditions (t, RH, ambient pressure, air flow rate, pressure drop across ASME nozzle;
- Biological suspension information (test organism, suspension preparation, drying air, nebulizer pressure, initial volume, and time on);
- Biological sampling scheme (time run begins, sample length, and media); and
- Rotameter readings showing the flow rate through the bioaerosol sampler.

The organism counts are entered in the project notebook or recorded by a computer. If recorded to a computer, the file will be saved to the hard drive and later copied to a floppy disk or shared directory for backup.

## **A9.2: QA Reports**

The RTI QM will perform a system audit based on the approved T/QAP during the first month of testing; this is considered suitable since this testing program is using well-known measurement systems components. A report will be prepared for the task leader within 15 days of completion of the audit.

RTI will cooperate with audits performed by the EPA project officer, EPA QM, or their designee.

### **A9.3: Reporting**

After the completion of verification tests, the control test data, sample inventory logs, calibration records, and certificates of calibration will be stored. Calibration records will include such information as the instrument being calibrated, raw calibration data, calibration equations, analyzer identifications, calibration dates, calibration standards used and their traceabilities, identification of calibration equipment used, and the staff conducting the calibration. Final reports of self-assessments and independent assessments (i.e., technical systems audits, performance evaluations, and audits of data quality — TSAs, PEs, and ADQs — will be retained. Each verification report and verification statement will contain a QA section, which will describe the extent that verification test data comply with DQOs.

### **A9.4: Verification Reports and Verification Statements**

Verification reports and verification statements will be prepared by the task leader and reviewed by the APCT Center director and the APCT Center quality manager prior to submittal to the EPA project officer for approval. Procedures for the preparation, review, and dissemination of verification reports and verification statements are described in the U.S. EPA, Environmental Technology Verification Program Quality Management Plan<sup>11</sup>.

It is anticipated that the verification reports and statements will include the filtration efficiency of the tested device for the challenges used for the clean and dust-loaded device.

The following information will be included in the verification reports and verification statements, depending on which test(s) were performed:

- The fractional filtration efficiency of the air device over the 0.03 - 10  $\mu\text{m}$  size range for the device when (1) clean, and if applicable (see A5) (2) conditioned and (3) fully dust-loaded;
- The efficiency for the four bioaerosols;
- The pressure drop across the clean and (if applicable, see A5), fully dust-loaded device;
- The test air flow rate;
- The measured MERV and the associated E1, E2, and E3 values of the ASHRAE 52.2-1999 test;
- A complete ASHRAE 52.2 report, and
- A description and photograph of the device tested.

## **SECTION B: MEASUREMENT/DATA ACQUISITION**

### **B1: Test Design**

Under this T/QAP, the following tests may be performed:

1. A complete ASHRAE 52.2-1999 test,
2. Bioaerosol test with four culturable microorganisms,
3. Inert particle tests, using KCl aerosol:
  - a. 0.3 – 10  $\mu\text{m}$ , with OPC measurement,
  - b. 0.03 – 0.3  $\mu\text{m}$ , with SMPS measurement, and
  - c. 0.03 – 10  $\mu\text{m}$ , with combined SMPS and OPC measurements.

The above tests will be performed on clean, conditioned and dust-loaded devices as applicable. Conditioning with the sub-micron aerosol and dust loading will be required for all devices that incorporate filter media. All tests will be performed on devices at an air flow rate acceptable under ASHRAE 52.2-1999.

### **B1.1: ASHRAE 52.2-1999 and Inert Testing**

The ASHRAE 52.2-1999 test will be run in accordance with the ASHRAE 52.2-1999 test method. A second device will use modified ASHRAE 52.2-1999 procedures to extend the measurements to smaller particle sizes and to condition electret media. All the inert aerosol tests will use laboratory-generated KCl particles dispersed into the airstream as the test aerosol. A particle counter will measure and count the particles in a series of size ranges both upstream and downstream of the test devices for its efficiency determinations. To simulate the effects of dust accumulation on the devices, the devices will be tested when clean and, if applicable (see A5), when conditioned and when fully dust-loaded. The dust-loading will follow ASHRAE 52.2-1999 procedures as applicable.

#### **B1.1.1: Particle Counters**

For the inert aerosol filtration efficiency measurements, the particle sizing measurements will be made with two particle counting instruments: a Climet Model 500 spectrometer (OPC) covering the particle diameter size range from 0.3 - 10  $\mu\text{m}$  in 12 particle sizing channels and a TSI SMPS to cover the range from 0.03 - 0.3  $\mu\text{m}$ . For the conditioning aerosol, a TSI condensation particle counter (CPC) (model 3022A or similar) will be used to monitor the upstream concentration. The CPC will function to monitor the concentration of the submicrometer-sized particles used for conditioning; it will not aid in measuring the efficiency of the devices.

The OPC uses a laser-light illumination source and has a wide collection angle for the scattered light. The OPC's sampling rate is 7.1 L/min. (0.25 cfm). The OPC is equipped to provide a contact closure at the end of each sample and also provides a 15 sec. delay in particle counting after each sample. The contact closure is used to control the operation of electromechanical valve actuators in the upstream and downstream sample lines. The 15 sec. delay allows time for the new sample to be acquired. The SMPS consists of a TSI Model 3080 electrostatic classifier and a TSI Model 3010 or 3022 CPC.

Depending upon the quality of the data from any individual test, the SMPS can sometimes reliably quantify particles even smaller than 0.03  $\mu\text{m}$ , and when this is the case, those smaller

sizes are reported. The ability to quantify sizes smaller than  $0.03\ \mu\text{m}$  is determined as defined in Table A2. A data control parameter for the SMPS requires that the coefficient of variance (CV) on upstream counts be computed for each efficiency test based on the upstream particle counts and that the CV be less than 0.30 before the data is used. The lower size ranges for the SMPS are included in the verification report only if they meet the data control parameter. Particle sizes above  $0.3\ \mu\text{m}$  will be measured and reported when there are particle counts that meet the data specifications; however, the aerosol generation system necessary to meet our data standards often does not achieve sufficient particle counts for the larger particles.

### **B1.1.2: Inert Aerosol Generation**

Three aerosol generators will be used for the tests as applicable. These generators are needed to cover the range of particle sizes needed; one for the  $0.03 - 0.3\ \mu\text{m}$  tests, one for the  $0.3 - 10\ \mu\text{m}$  tests, and one to generate the submicrometer conditioning aerosol. All of the aerosols will be generated from KCl in aqueous solution. The concentrations of KCl will vary as will the generation technique to give particles in the needed size ranges.

For the  $0.3 - 10\ \mu\text{m}$  efficiency tests, the KCl solution will be nebulized using a two-fluid (air and liquid) atomizing nozzle (Spray Systems 1/4 J siphon spray nozzle). The full description of the test duct is in Appendix A. The nozzle is positioned at the top of a  $0.30\ \text{m}$  (12 in.)-diameter,  $1.3\ \text{m}$  (51 in.)-tall transparent acrylic spray tower. The tower serves two purposes. It allows the salt droplets to dry by providing an approximately 40 sec. mean residence time, and it allows larger particles to fall out from the aerosol. After generation, the aerosol passes through a TSI Model 3054 aerosol neutralizer (Krypton-85 radioactive source) to neutralize any electrostatic charge on the aerosol (electrostatic charging is an unavoidable consequence of most aerosol-generation methods). The KCl solution is fed to the atomizing nozzle at  $1.2\ \text{mL/min.}$  by a pump. Varying the operating air pressure of the generator allows control of the output aerosol concentration.

For the  $0.03 - 0.3\ \mu\text{m}$  tests, the KCl solution will be nebulized with a Collison nebulizer or Laskin nozzle generator. Both of these devices generate smaller particles than the spray nozzle.

### **B1.1.3: Inert Conditioning Procedure for Devices with Media Under Test Options 2 and 3**

For the conditioning required for devices with filter media if tested under options 2 or 3, the conditioning aerosol will be produced using a bank of Laskin generators nebulizing a 0.1% KCl aqueous solution (1 g KCl to 1 L of water). This is a refinement of procedures developed by RTI on earlier EPA-supported research<sup>7</sup> and under ASHRAE research project 1190-RP. Previous measurements have indicated that the resultant aerosol is  $< 0.1\ \mu\text{m}$  in mean diameter. Periodically during the conditioning portion of the test, the device's efficiency will be measured ( $0.3 - 10\ \mu\text{m}$ ) to determine if the efficiency has fallen to its minimum condition. Once the efficiency is at or near its minimum, the conditioning will cease. The duration of conditioning and the concentration of the conditioning aerosol will be monitored during the test.

### **B1.2: Culturable Bioaerosol Testing**

The bioaerosol testing is based on the inert methodology and uses the same test rig as the inert aerosol. The methodology is described in ML SOP #038\* (SOP for the Determination of the Filtration Efficiency of Bioaerosols). Two primary differences from the inert aerosol methodology are that the bioaerosol is generated from a suspension of the test organism and the

\* All SOPs are maintained on file at RTI indefinitely. Access to these files is permitted onsite at RTI.

sampling is achieved using bioaerosol samplers. The use of microorganisms as the challenge aerosol requires that a number of technical issues be addressed. These include:

- Measuring the survivability and culturability of the organisms through the aerosol generation and collection process;
- Determining whether the test organisms are being aerosolized as singlets with a narrow size distribution;
- Generating the bioaerosol challenge in sufficient concentration to maintain the sampling duration within the sample time limits of the bioaerosol sampler; and
- Establishing the generation protocol for the test organisms.

While all of these issues have been addressed in earlier RTI work, they may need to be readdressed based on the specific organisms used and the technologies being tested.

### **B1.2.1: Test Organisms**

The size and shape of the organisms selected for testing are important because the organisms are aerosolized and their filtration efficiency determined. These organisms naturally vary in both their sizes and shapes. Therefore, there is the need to select organisms that reflect that natural diversity.

The bioaerosol tests will be conducted using four organisms: one fungal spore, one spore-forming bacterium, one vegetative bacterium, and one virus. The fungal spore (2 - 3.5  $\mu\text{m}$  spheres), *Aspergillus versicolor*, is frequently reported as a causative agent of hypersensitivity pneumonitis and has been isolated from a number of problem buildings. The spore form of the bacteria *Bacillus atrophaeus* (formerly *B. subtilis var niger*) is elliptically shaped with dimensions of 0.7 - 0.8 x 1 - 1.5  $\mu\text{m}$ . The organism is a ubiquitous environmental bacterium found at high levels in soil and highly associated with indoor dust. *Staphylococcus epidermidis* is a common gram-positive 0.5 - 1.5  $\mu\text{m}$  spheres organism and will be the representative vegetative bacterium.

Human viruses are thought to be spread by airborne or droplet transmission. Because human viruses can be expensive and cumbersome to work with, the bacterial virus (bacteriophage) MS2 (0.02 - 0.03  $\mu\text{m}$ ), having approximately the same aerosol characteristics as a human virus, will serve as a surrogate for the viruses of similar and larger size and shape.

Although the individual virus particles are in the submicrometer size range, the test particle size planned for the virus tests will span a range of sizes (polydispersed bioaerosol). This test is not designed to study the removal efficiencies for single individual virus particles; rather, it is designed to determine the removal efficiencies for virus particles as they are commonly found indoors. A representative challenge would be a polydispersed aerosol containing the phage because:

- The aerosols created from sneezing and coughing vary in size from  $< 1$  to 20  $\mu\text{m}$ <sup>12</sup>, but the largest particles settle out and only the smaller sizes remain in the air for extended periods for potential removal by an air cleaner;
- For some viruses (i.e., Coxsackie virus), few viruses have been found associated with the smallest particles<sup>13</sup>; and
- Nearly all 1 - 2  $\mu\text{m}$  particles are deposited in the respiratory tract, while larger particles may not be respired.

### **B1.2.2: Bioaerosol Preparation and Generation**

Bacteria suspension preparation for the aerosolization process requires that the specific test organism be grown in the laboratory and the suspension prepared for aerosol generation in the test rig following ML SOP #012 (SOP for the Quantitation of Viable Microorganisms in Suspension). The microbial challenge suspensions are prepared by inoculating the test organism on solid or liquid media, incubating the culture until mature, wiping organisms from the surface of the pure culture (if solid media), and eluting them into sterile nebulizing fluid to a known concentration, corresponding to a concentration of approximately  $1 \times 10^7$  CFUs (colony forming units)/mL. Trypticase soy agar will be used for the bacteria. Sabourauds Dextrose Agar will be used for the fungus.

The phage challenge will be prepared by inoculating a logarithmic phase broth culture of the host bacteria with phage and allowing it to multiply overnight or until the majority of the host bacteria are lysed. The mixture is processed to collect and concentrate the phage. Then, the phage stock is filter sterilized ( $0.2\mu\text{m}$ ) to remove the bacteria. The phage stock will be used as the challenge aerosol. The concentration of the phage stock will be approximately  $1 \times 10^{12}$  or higher plaque forming units (PFU)/mL.

The challenge organism suspensions will be aerosolized using a Collison nebulizer (BGI, Waltham, MA) at 15 psi air pressure. The Collison nebulizer generates droplets with an approximate volume mean diameter of  $2\mu\text{m}$ . The particle diameter after the water evaporates depends on the solids content of the suspension. Particle size is determined by the size of the suspended particles (if singlets).

Upstream and downstream sampling of the bacteria and fungus will be accomplished using a one-stage Andersen viable bioaerosol sampler. The one-stage Andersen sampler is a 400-hole multiple-jet impactor operating at 28 L/min. The  $d_{50}$  (50% cut point on Andersen sampler) is  $0.65\mu\text{m}$ . After sampling, the petri dishes will be removed from the sampler and incubated at appropriate times and temperatures for the test organism being used. CFUs are then enumerated and their identity confirmed.

The phage will be collected in all glass impingers (AGIs). The AGI is a high velocity liquid impinger operating at a flow rate of 12.3 - 12.6 L/min. The  $d_{50}$  is approximately  $0.3\mu\text{m}$ . The AGI is the sampler against which the other commonly used bioaerosol samplers are often compared. The AGI (containing collection fluid) will be used for the MS2 sampling.

The experimental conditions and sampling times will be adjusted so that these samplers will be used within their upper and lower sampling limits.

To quantify the microbial counts, the plates are incubated at the appropriate temperature and time for the test organism (overnight to a week). Colonies or plaques are counted. A "positive-hole" correction is applied<sup>14</sup> to the one-stage Andersen data to correct for undercounting at high concentrations.

## **B2: Sampling Methods Requirements**

Inert aerosol sampling method requirements and critical dimensions and configurations of the test apparatus are specified in ASHRAE 52.2-1999. Bioaerosol sampling methodology will comply where appropriate. Bioaerosol samplers are operated according to the manufacturer's specifications. The vacuum pumps required for operating the samplers are calibrated following ML SOP #029 (SOP for Calibrating Pump Flows Using a Dry Gas Meter).

## **B3: Sample Handling and Custody Requirements**

Sampling methods and laboratory procedures are described in specific laboratory SOPs. These SOPs address any anticipated failures and the methods that will be employed to overcome these failures. Most of the methods are well-known sampling methods; therefore, sampling failures are not anticipated. Any additional project-specific considerations will be addressed by the RTI technical leads and included in an updated SOP. Supporting measurements, such as temperature, relative humidity or atmospheric pressure, will be recorded in laboratory data logs, run sheets or notebooks.

Upon receipt of the test devices, each will be serially numbered using a permanent marker (or other means as appropriate). All devices for this study will be stored in a single indoor, air conditioned common area (Bay 1).

## **B4: Analytical Methods Requirements**

The analytical method requirements for the inert aerosol testing are described in ASHRAE 52.2-1999. The requirements for biological testing are described in the appropriate ML SOPs.

## **B5: Quality Control Requirements**

The apparatus will be tested to verify that the test rig and sampling procedures are capable of providing quantitatively reliable particle size measurements. Appendix A contains quality control information for inert aerosols (Table A1), the scanning mobility particle sizer (Table A2) and bioaerosols (Table A3).

## **B6: Instrument/Equipment Testing, Inspection, and Maintenance Requirements**

Qualification tests will be conducted as required by the table shown in Appendix A. Typically, these tests are run as part of each test run, monthly, biannually, or after a change that may alter performance.

## **B7: Instrument Calibration and Frequency**

Calibration will be performed in accordance with the manufacturer's recommendations or annually. Recommended instrument calibration frequencies are provided in the respective SOPs and manufacturer's manuals. Pipettes will be calibrated gravimetrically following ML SOP #013 (SOP for Pipet Calibration).

## **B8: Inspection/Acceptance Requirements for Supplies and Consumables**

Chemicals, supplies, and other consumables will be purchased from sources that have provided high quality products to the laboratory in the past. Materials such as growth media will be purchased from a single source to help ensure uniformity throughout the duration of the project.

All supplies will be inspected by the lab personnel. RTI's purchasing department will assist with the return of any equipment or materials that do not meet project requirements.

### **B9: Data Acquisition Requirements (Non-direct measurements)**

Non-measurement sources such as computer databases, programs, literature files, or historical databases will not be used for data acquisition.

Manual methods of primary data acquisition (e.g., visual CFU counting) are described in ML's SOPs, while automated data acquisition equipment (e.g., balances and environmental controls) is checked using procedures recommended by the manufacturer. Procedures for screening and verifying manually entered data are used to reduce input errors to a minimum through double checking each other. Non-experimental data, such as an MSDS, will be included in the project notebook and a copy maintained in the RTI Technical Leader's project file.

### **B10: Data Management**

The work performed using this T/QAP will conform to the quality management plan for the APCT Center<sup>15</sup>.

Guidelines for data management in the ML include the description, location, format, and organization of all types of records. The technical leaders will oversee all data management activities. This section identifies the activities and processes planned for documenting the traceability of the data, calibrations, and information in the verification report.

#### **B10.1: Data Recording**

Data for this task will be collected either by computer or by manual (handwritten) entries. Observations and records (e.g., sample description and collection information) will be recorded manually in lab notebooks kept exclusively for this task. Output data generated by the OPC instruments will be transferred directly to a computer file and stored as a spreadsheet; printed output will be taped into the lab notebook.

#### **B10.2: Data Analysis**

##### **B10.2.1: Inert Aerosol Data**

The computation of inert aerosol filtration efficiency is based on the ratio of the downstream-to-upstream particle concentrations corrected on a channel-by-channel basis for:

- Background counts (i.e., upstream and downstream counts observed when the aerosol generator is off) and
- For the correlation ratio measured at the start of the test sequence.

A minimum of two background and six upstream and six downstream counts will be taken. These data will be used for determining filtration efficiency by computing the observed penetration ( $P_{\text{observed}}$ ) (Eq. 1):

$$P_{\text{observed}} = \frac{(D - D_b)}{(U - U_b)} \quad \text{Eq. 1}$$

where:

D = Downstream particle count,



$D_b$  = Downstream background count,  
 $U$  = Upstream count, and  
 $U_b$  = Upstream background count.

To remove system bias, the observed penetration is corrected by the correlation ratio (R) (the  $P_{\text{observed}}$  measured during a blank control test for which no device is installed in the duct) (Eq. 2).

$$P_{\text{corrected}} = P_{\text{observed}} / R \quad \text{Eq. 2}$$

The inactivation efficiency is then computed (Eq. 3).

$$\text{Inactivation Efficiency (\%)} = 100(1 - P_{\text{corrected}}) \quad \text{Eq. 3}$$

### B10.2.2: Bioaerosol Data

Data analysis will be performed using commercially available software (Microsoft Excel<sup>16</sup>) to enter the raw data into a spreadsheet and calculate results from a series of equations.

Samples will be collected simultaneously using multiple samplers. A minimum of six, usually twelve, replicates will be collected for each efficiency determination.

The mean upstream and downstream CFUs will be calculated as (Eq. 4):

$$\bar{U} = \frac{\sum_{i=1}^n U_i}{n} \quad \text{and} \quad \bar{D} = \frac{\sum_{i=1}^n D_i}{n} \quad \text{Eq. 4}$$

where:

$D_i$  = Downstream count of the  $i$ th sample and  $n$  is the number of replicate samples collected and  
 $U_i$  = Upstream count of the  $i$ th sample and  $n$  is the number of replicate samples collected.

The calculation of the penetration is based on the ratio of the downstream to upstream culturable counts. The penetration with the device installed in the test rig ( $P_{\text{measured}}$ ) is shown in the following equation (Eq. 5):

$$P_{\text{measured}} = \bar{D} / \bar{U} \quad \text{Eq. 5}$$

where:

$\bar{D}$  = Mean downstream count with a device installed in the test rig and  
 $\bar{U}$  = Mean upstream count with a device installed in the test rig.

The  $P_{100}$  (no device installed in the test rig) is calculated as the  $P_{\text{measured}}$  but using the results of the no device tests (Eq. 6).

$$P_{100} = \frac{\overline{D}_{100}}{\overline{U}_{100}} \quad \text{Eq. 6}$$

where:

$$\begin{aligned} \overline{D}_{100} &= \text{Mean downstream count with no device in the test rig and} \\ \overline{U}_{100} &= \text{Mean upstream count with no device in the test rig.} \end{aligned}$$

To remove system bias, the  $P_{\text{measured}}$  is corrected by the penetration of a blank “no device” test for which no air cleaner is installed in the duct ( $P_{100}$ ) (Eq. 7).

$$P_{\text{corrected}} = \frac{P_{\text{measured}}}{P_{100}} \quad \text{Eq. 7}$$

The inactivation efficiency is then calculated as shown in Eq. 8.

$$\text{Inactivation Efficiency (\%)} = 100(1 - P_{\text{corrected}}) \quad \text{Eq. 8}$$

The precision DQO for bioaerosol inactivation efficiency will be calculated based as  $\pm$  one standard deviation of penetration computed from the coefficient of variance of upstream and downstream culturable counts as shown in Eq. 9.

$$\text{Std. Deviation} = P_{\text{measured}} (\sqrt{CV_U^2 + CV_D^2}) \quad \text{Eq. 9}$$

where:

$$\begin{aligned} P_{\text{measured}} &= \text{Penetration calculated from the upstream and downstream culturable counts,} \\ CV_U &= \text{Coefficient of variance for the upstream counts, and} \\ CV_D &= \text{Coefficient of variance for the downstream counts.} \end{aligned}$$

### B10.3: Data Storage and Retrieval

Laboratory notebooks containing manually recorded information and data output generated from instrumentation will be stored in the custody of the appropriate technical lead for the duration of the project.

Spreadsheet files including raw and calculated data will be stored on computers. The files will be downloaded to a network server backed up nightly on magnetic tape.

Following policy at RTI, as well as ETV policy, project files will be archived offsite at a secure facility for a minimum of 7 years following the end of the project.

## SECTION C: ASSESSMENT/OVERSIGHT

### C1: Assessments and Response Actions

#### C1.1: Audits

RTI will be subject to both external and internal audits as specified in the APCT Center Quality Management Plan (QMP)<sup>17</sup> (Table 3) and the ETV QMP<sup>11</sup> (Table 9-1), ETV Assessments. A subset of those tables is shown below, Table 3. Audits based on this test/QA plan include Technical System Audits (TSAs) and Performance Evaluation Audits (PEAs). The raw and summary data is subject to Audits of Data Quality (ADQs). An external audit may be conducted by EPA or a designated representative. The auditor(s) will document their findings and note where corrective actions are necessary. The auditor(s) will distribute audit reports to those listed in Section A3 as well as to the supervisor whose laboratory was audited.

**Table 3. RTI's ETV Assessments**

Assessment Tool	Assessors	Subject of Assessment	Minimum Frequency	Reason for Assessment	Report Reviewed by
Technical Systems Audits	<u>Self</u> RTI QAM  <u>Independent</u> EPA QAM	Test/QA plan	<u>Self</u> Once per test or batch of tests  <u>Independent</u> Once per year	Assess technical quality of evaluations	EPA Project Officer  APCT Center Director  Task Leader
Performance Evaluation Audits	<u>Self</u> RTI QAM  <u>Independent</u> EPA QAM	Test/QA plan	<u>Self</u> Each test or batch of tests  <u>Independent</u> Each test or batch of tests	Assess measurement performance	EPA Project Officer  APCT Center Director  Task Leader
Audits of Data Quality	<u>Self</u> RTI QAM  <u>Independent</u> EPA QAM	Raw data and summary data	<u>Self</u> At least 10% of the data in each test  <u>Independent</u> Each test	Assess data calculations and reporting	EPA Project Officer  APCT Center Director  Task Leader

#### C1.2: Corrective Actions

Technical personnel will have the direct responsibility for ensuring that the T/QAP plan is implemented, that the operating parameters are within acceptable limits as specified in Appendix A, and that corrective actions are taken when appropriate. Corrective action will be taken whenever measurement accuracy or bias is outside the limits of objectives for the critical measurements. If procedures are found to be faulty, corrective action will also be taken.

Corrective actions include:

- Problem identification;
- Attempting to find the cause;
- Attempting immediate repairs (if possible);
- Reporting or documenting the problem;
- Planning for corrective action (if major repairs are needed);

- Checking that problem was corrected;
- Documenting the corrective actions taken; and
- Recommending changes to instruments, SOPs, etc. to avoid similar future occurrences.

The RTI QM, task leader, and the technical leaders will be jointly responsible for proper documentation of corrective actions. Minor corrective actions are to be recorded in the laboratory notebooks. Major problems will be addressed as outlined above. All corrective actions will be noted in the test report. Depending on the time and expense involved with necessary corrective actions, it will be necessary to consult the EPA project officer or the sponsor before implementing any changes in the planned activities.

### **C2: Reports to Management**

The task leader will notify the APCT Center director and EPA project officer when testing under this project is being conducted. The task leader will submit verification reports and verification statements, as well as data, to the RTI QM. After technical assessments, the task leader will submit the assessment report to the APCT Center director. The APCT Center director will submit verification reports and verification statements to the EPA project officer and will submit assessment reports to the EPA project officer for informational purposes.

Audit reports will be sent to all those on the distribution list for the T/QAP.

## **SECTION D: DATA VALIDATION AND USABILITY**

### **D1: Data Review, Validation, and Verification Requirements**

The test is acceptable if all the measured parameters fall within the DQO limits described in Table 2. The test operator and analyst are responsible for checking that all measured parameters fall within prescribed limits before continuing testing.

### **D2: Validation and Verification Methods**

The test analysis will verify that the test data have been correctly entered and processed by double checking each other. Newly-developed or modified software, including spreadsheets, will be checked for correctness before being used to process project data. All manual calculations will be double-checked.

Each verification report will be reviewed by the RTI QM for compliance with the applicable method and for the quality of the data reported.

The RTI QM will check for the following:

- Data completeness,
- Initial and continuing calibrations, and
- QC reference and internal standards.

### **D3: Reconciliation with Data Quality Objectives**

Each ETV verification statement will summarize testing conditions and will state test results. Each ETV test report will present the critical and relevant ancillary measurements.

Actual data quality will be compared with the DQOs specified in Section A7; if the data quality meets or exceeds the objectives and test specifications have been met, the test data will be considered acceptable. If exceptions are identified, the issues will be investigated for impact on the credibility of the data, the EPA QM will be consulted, and the test results disposed of on the basis of this careful consideration; the verification statement will note the exception(s) and their potential impact on the utility of results.

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#### **ML SOPs Used in this Document**

1. ML SOP #012, SOP for the Quantitation of Viable Microorganisms in Suspension.
2. ML SOP #013, SOP for Pipet Calibration.
3. ML SOP #029, SOP for Calibrating Pump Flows Using a Dry Gas Meter.
4. ML SOP #038, SOP for the Determination of the Filtration Efficiency of Bioaerosols.

## Appendix A: Test Specifications

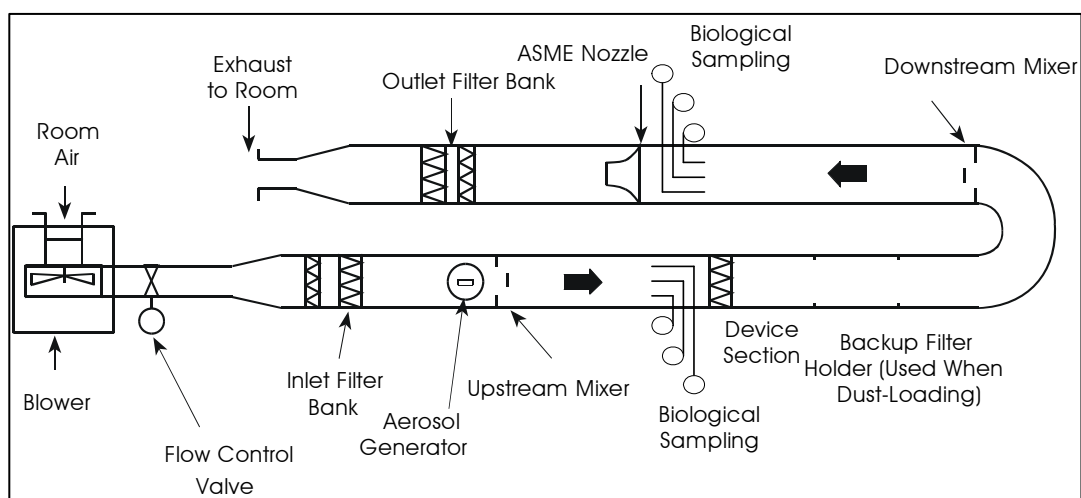
Test specifications for the inert aerosol tests are defined in ASHRAE 52.2-1999 and shown in Table A1. These will be used for both the ASHRAE 52.2-1999 testing and the inert aerosol component of the bioaerosol test. The test specifications associated with the SMPS and the conditioning aerosol are found in Table A2. Table A3 shows the test specifications for the bioaerosol test. The test duct performance specifications applicable to all testing are found in Table A4.

### Test Duct /System

A schematic of the test duct is shown in Figure A1. The drawing is approximately to scale. The test duct is a 610 mm (24 in.) x 610 mm (24 in.) square. The locations of the major components, including the sampling probes, test section (device holder), the aerosol generator (site of aerosol injection) are shown.

There are presently no standards available to directly “calibrate” the test system for penetration. However, a number of parameters can be checked to verify proper performance. 0% and 100% penetration measurements are made by using a HEPA filter and an empty (no device) test section, respectively, using the optical particle counter (OPC) and KCl as the inert particulate. Separate tests with the bioaerosol will be done using the test bioaerosol and the bioaerosol samplers.

The flow rate will be measured via the pressure drop across an ASME long radius flow nozzle (i.e., nozzle size 8½ in.) mounted in the center of the duct downstream of the device. It will be the primary standard for the laboratory. Prior to use, the nozzle is visually inspected to be free from defects. The installation of the nozzle in the duct will be inspected to confirm that it is seated in place.



**Figure A1.** Schematic of test duct (top view) used for filter testing. Drawing is approximately to scale with the duct being 610 x 610 mm<sup>2</sup> (24 x 24 in.<sup>2</sup>) and shows the location of aerosol injection, mixing baffles, test section, ASME flow nozzle, and OPC sampling probes.



The pressure drop across the device will be measured with an inclined manometer and/or a digital micromanometer. The zero and level of the manometer will be confirmed and connecting tubing inspected for integrity.

Measurements of the in-duct temperature and relative humidity (RH) and room atmospheric pressure will be made. These measurements are not critical to the program and are being collected simply to document the general test environment. A wet and dry bulb psychrometer will be used for determination of temperature and relative humidity and an aneroid barometer for atmospheric pressure (periodically compared to a mercury barometer in an adjoining lab). For the bioaerosol, the RH goal is 20 – 70%. No specific quality control checks on these instruments are planned other than an inspection of the instruments for mechanical faults (e.g., mercury separation in the thermometers, poor tubing connections), and inspection of the data for reasonableness.

**Table A1. Quality Control Parameters For Inert Aerosol Tests**

Parameter	Frequency and description	Control Limits								
Minimum counts per OPC <sup>a</sup> channel for challenge aerosol	For each efficiency test, the total number of particles counted per OPC sizing channel for the upstream challenge aerosol is computed.	Minimum total of 500 particle counts per channel.								
Maximum total OPC count per sample	Each efficiency test.	Not to exceed maximum challenge aerosol concentration determined in the OPC upper concentration limit test referenced in Table A4.								
100% Efficiency test (0% Penetration)	Monthly. A HEPA filter is used for the test device.	Measured penetration must be <1%.								
100% Penetration (correlation test)	A 100% penetration test performed at least once per week during testing.	<table><tr><td>Particle Size range</td><td>Acceptable Penetration Range:</td></tr><tr><td>0.3 to 1 μm:</td><td>0.90 to 1.10</td></tr><tr><td>1 to 3 μm:</td><td>0.80 to 1.20</td></tr><tr><td>3 to 10 μm:</td><td>0.70 to 1.30</td></tr></table>	Particle Size range	Acceptable Penetration Range:	0.3 to 1 μm:	0.90 to 1.10	1 to 3 μm:	0.80 to 1.20	3 to 10 μm:	0.70 to 1.30
Particle Size range	Acceptable Penetration Range:									
0.3 to 1 μm:	0.90 to 1.10									
1 to 3 μm:	0.80 to 1.20									
3 to 10 μm:	0.70 to 1.30									
Penetration error limit for OPC data	Each test. Statistical check of data quality. Expected to be achieved on tests of clean air cleaners. May not always be achieved with dust-loaded air cleaners if the air cleaner sheds a significant amount of the collected dust.	<p>Per definitions and procedures of ASHRAE 52.2 Section 10.6.4<sup>6</sup></p> $\sigma \frac{\tau}{\sqrt{n}} \leq 0.07 P \text{ or } 0.05 \text{ whichever is greater for } 0.3 - 3 \mu\text{m}$ $\sigma \frac{\tau}{\sqrt{n}} \leq 0.15 P \text{ or } 0.05 \text{ whichever is greater for } 3 - 5.5 \mu\text{m}$ $\tau$								
OPC calibration: primary calibration	Primary calibration performed by manufacturer at manufacturer-specified intervals; but at least annually.	Manufacturer provides certificate of calibration.								

Parameter	Frequency and description	Control Limits
Minimum counts per OPC <sup>a</sup> channel for challenge aerosol	For each efficiency test, the total number of particles counted per OPC sizing channel for the upstream challenge aerosol is computed.	Minimum total of 500 particle counts per channel.
OPC sizing accuracy check: polystyrene latex spheres (PSL)	Daily. Sample aerosolized PSL spheres.	Peak of distribution should be in correct OPC channel.
OPC reference filter check	A filtration efficiency test is performed on a reference filter monthly during testing.	Efficiency must be consistent with reference filter measurements made after OPC's primary calibration; efficiency within $\pm 10$ percentage points.
OPC zero count	Each correlation and initial efficiency test.	Less than 10 counts per sample.
Background count rate	Measured during correlation and clean device tests.	Upper 95% confidence limit on background counts must be less than 5% of challenge counts.
Pressure drop across empty test section	Each correlation test.	Measured pressure drop must be $< 0.03$ in. H <sub>2</sub> O.
Pressure drop across the air cleaner	Annual. Compare to reference manometer.	Inclined fluid manometer or digital manometer readable to within $\pm 0.01$ in. H <sub>2</sub> O. 10% or better accuracy.
Pressure drop across the ASME flow nozzle used for measurement of airflow	Annual. Compare to reference manometer.	Inclined fluid manometer or digital manometer readable to within $\pm 0.01$ in. H <sub>2</sub> O. 10% or better accuracy.
Aerosol charge neutralizer	Monthly. Confirm activity of radioactive charge neutralizers. Confirm balance of corona discharge neutralizers.	Activity must be detected in radioactive neutralizers. Corona discharge neutralizers must be in balance.
Filter weight	Filters will be weighed before and after completion of dust loading.	Electronic balance with 0.1 g resolution, 10% accuracy or better, calibrated annually.
Weight of ASHRAE dust fed into the test duct	Each test based on the change in weight of the dust on the dust-loading tray.	Electronic balance with 0.1 g resolution, 10% accuracy or better, calibrated annually.

<sup>a</sup> OPC = optical particle counter

**Table A2. Quality Control Parameters Associated with Scanning Mobility Particle Sizer (SMPS) and Conditioning Aerosol**

Parameter	Frequency and description	Control Limit
0% Efficiency test (100% Penetration)	At least once every five efficiency tests. A 100% penetration test is performed with no device in the test section.	Particle Size range 0.01 – 1.0 $\mu\text{m}$ Acceptable Penetration Range: 0.70 to 1.30
SMPS: CV on upstream counts	Computed for each efficiency test based on the upstream particle counts.	< 0.30
Conditioning aerosol concentration	Measured with a condensation particle counter (CPC).	Concentration will not exceed instrument's specified concentration limit.
SMPS operational checks:		
sizing accuracy check	At start of project and at least monthly during testing, sample aerosolized monodisperse PSL spheres.	A relative peak in the number distribution is observed within 20% of the PSL particle diameter
instrument flow rates	Confirmed prior to test program using reference flow meter.	Flows should be within 10% of set points.
instrument zero — filtered inlet	Checked at start of project and weekly during testing.	< 0.1 particle/cm <sup>3 a</sup> counted by CPC.
instrument zero — 0 volt setting	Checked at start of project and weekly during testing.	< 0.1 particles/cm <sup>3</sup> counted by CPC.
inlet impactor	Visually confirm impactor orifice is free of debris and that the impactor plate is greased. Daily.	Orifice clear of visible obstructions. Impactor has very thin film of vacuum grease.
photodetector	Check at start of program. Filter on CPC inlet and/or sample pump off.	0 $\pm$ 0.05 volts
Reference flow meter	Bios International Model DryCal DC1 Primary Air Flow Meter (soapless piston-type cell) or the Gilibrator (good for lower flowrates). Used to confirm SMPS flow rates at beginning of program.	Based on the fundamental nature of this positive displacement piston flow meter, the manufacturer's accuracy claim is accepted. The unit is visually inspected for proper operation prior to use.
Reference manometer	TSI Model 8702/8704 digital manometer and/or Meriam Model 50MH10-8 inclined fluid manometer.	Digital manometer to receive primary calibration by manufacturer within prior 12 months. Fluid manometer inspected for zero and level.

<sup>a</sup> cm<sup>3</sup> = cubic centimeter

**Table A3. Quality Control Parameters for Bioaerosols**

Parameter	Frequency and description	Control Limits										
Minimum upstream counts for samplers	Each efficiency test.	Minimum of 10 CFU <sup>a</sup> /plate or PFU <sup>b</sup> /plate										
Maximum counts for samplers	Each efficiency test.	Maximum of 400 CFU/plate or 800 PFU <sup>b</sup> /plate										
100% Penetration (correlation test)	Performed at least once per test sequence per organism	<table><tr><td>Test Organism</td><td>Acceptable Penetration Range:</td></tr><tr><td><i>B. subtilis</i></td><td>0.85 to 1.15</td></tr><tr><td><i>S.epidermidis</i></td><td>0.80 to 1.20</td></tr><tr><td>MS2</td><td>0.80 to 1.20</td></tr><tr><td><i>A. versicolor</i></td><td>0.85 to 1.15</td></tr></table>	Test Organism	Acceptable Penetration Range:	<i>B. subtilis</i>	0.85 to 1.15	<i>S.epidermidis</i>	0.80 to 1.20	MS2	0.80 to 1.20	<i>A. versicolor</i>	0.85 to 1.15
Test Organism	Acceptable Penetration Range:											
<i>B. subtilis</i>	0.85 to 1.15											
<i>S.epidermidis</i>	0.80 to 1.20											
MS2	0.80 to 1.20											
<i>A. versicolor</i>	0.85 to 1.15											
Upstream CFUs	Each test. Statistical check of data	CV <sup>c</sup> ≤ 0.20										
Upstream PFUs	Each test. Statistical check of data	CV <sup>c</sup> ≤ 0.35										

<sup>a</sup> CFU = colony forming units

<sup>b</sup> PFU = plaque forming unit

<sup>c</sup> CV = coefficient of variance

**Table A4. Quality Control Parameters for the Test Duct**

Parameter	Control Limits								
Air velocity uniformity based on traverse measurements over a nine-point cross-sectional grid at the test flow rate. Performed upstream of the test section using a TSI Model 8345 digital thermal anemometer.	CV <sup>a</sup> < 10%								
Inert aerosol uniformity based on traverse measurements over a nine-point cross-sectional grid at the test flow rate. Performed upstream of the test section.	CV < 15%								
Inert downstream mixing based on nine-point perimeter injection grid at the test section and center-of-duct readings at the downstream probe locations.	CV < 10%								
100% Efficiency test based on HEPA filter test.	Efficiency > 99%								
100% Penetration (correlation test)	<table> <tr> <th>Particle Size range</th><th>Acceptable Penetration Range:</th></tr> <tr> <td>0.3 to 1 µm:</td><td>0.90 to 1.10</td></tr> <tr> <td>1 to 3 µm:</td><td>0.80 to 1.20</td></tr> <tr> <td>3 to 10 µm:</td><td>0.70 to 1.30</td></tr> </table>	Particle Size range	Acceptable Penetration Range:	0.3 to 1 µm:	0.90 to 1.10	1 to 3 µm:	0.80 to 1.20	3 to 10 µm:	0.70 to 1.30
Particle Size range	Acceptable Penetration Range:								
0.3 to 1 µm:	0.90 to 1.10								
1 to 3 µm:	0.80 to 1.20								
3 to 10 µm:	0.70 to 1.30								
OPC <sup>b</sup> upper concentration limit based on limiting the concentration to below the level corresponding to the onset of coincidence error.	No predetermined level, but must be established prior to testing.								
Aerosol generator response time	No predetermined level.								
Duct leakage Ratio of leak rate to test flow rate. Determined by sealing the duct at inlet HEPA filter bank and at the ASME flow nozzle locations followed by metering in air to achieve a steady duct pressure. The flow rate of the metering air (equal to the leakage flow) is measured for a range of duct pressures.	Ratio < 1.0%								
OPC zero count check	< 10 counts per sample								
OPC sizing accuracy check based on sampling aerosolized monodisperse PSL spheres of known size.	Relative maximum must appear in the appropriate sizing channel.								
Aerosol neutralizer activity (if radioactive source is used)	Radioactivity must be detected.								
Dust feeder air flow rate as function of discharge pressure based on measuring the required dust feeder air gauge pressure to achieve 425 L/min. (15 cfm) air flow.	No predetermined value.								
Final device efficiency Based on injecting 100 g of dust and computing weight change of the filter.	100 ± 2 g of dust captured for 100 g injected.								

<sup>a</sup> CV = coefficient of variance

<sup>b</sup> OPC = optical particle counter

## Appendix B: Inert Aerosol Run Sheet

Date: \_\_\_\_\_ Test Operator: \_\_\_\_\_ **Staple photo to back of page 2.**

### Physical Description of Device:

Test Requested by: \_\_\_\_\_ Charge Number: \_\_\_\_\_

Manufacturer: \_\_\_\_\_

Product Name: \_\_\_\_\_

Model: \_\_\_\_\_

Condition: New or From Field No damage or Slight frame damage and/or Media damage (Circle all that apply)

Other/describe damage: \_\_\_\_\_

Product type: \_\_\_\_\_

Other Attributes: \_\_\_\_\_

Height	Width	Thickness	Media Type (if applicable)	Media Color (if applicable)

### Correlation Test: (use 3/3 - 10/9 - 3/3 sampling)

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Flow rate manometer zeroed and level: \_\_\_\_\_ Device pressure drop manometer zeroed and level: \_\_\_\_\_

OPC clock correct: \_\_\_\_\_ Valve switch on: \_\_\_\_\_

### OPC: (Set for 0.10 ft<sup>3</sup> samples with 15 second purge; use 3/3 - 10/9 - 3/3 sampling)

OPE: (Set for 0.10 ft <sup>3</sup> samples with 15 second purge, use 3/3 - 10/7 - 3/3 sampling)											
20 min warm up  ✓	Flow is 0.25 cfm  ✓	CI-226 switch "Low" ✓ or n/a	Zero Check < 10 total / sample enter actual count*		Daily PSL check (Enter size when performed or ✓ if done earlier today)	File Name c:\climet\rpmmddyyss R P MM DD YY SS					
			HEPA capsule or In-duct								
			**		**						

\* must meet <10 criteria at least once per ASHRAE 52.2 test. Notify project manager if limit is exceeded.

\*\* Save daily check to disk using file name. RPMDDYY-HEPA-PSL.TXT

**Test Conditions:**

Flow rate (cfm) <sup>++</sup>	Flow Manometer (inch H <sub>2</sub> O)	Dry Bulb Temp. (F) Limits = 50-100 °F	Wet Bulb Temp. (°F)	RH Limits = 20-65%	Atm Pressure (inches Hg) xx.xx

<sup>++</sup> Is flowrate MERV eligible for this size device? Y or N (see page 3)

**Aerosol Generator: "No-Device" Pressure Drop**

Aerosol Type	Pump setting	Drying Air	Nozzle air pressure (psi)	Nozzle air flowmt.	Upper Concentration Target *	Lower Concentration target **	At start of test x.xx(x)	At end of test x.xx(x)
KCL	1.2cc/ min	4 cfm 240 cfh			enter Ch 1 count	enter Ch 15 cnt	must be < 0.03"	must be < 0.03"

\* Channel 1 targets: CI-500 = 3,000; CI-Spectro = 3,000; CI-226 = 5,000 - 150 counts per sample desired range.  
 \*\* Channel 15 target: 72  
 Notify project manager if these targets are not met.

Using "Correlation" graph in spreadsheet, does data look reasonable? \_\_\_\_ yes \_\_\_\_ no (Should be near 1.0)

## Appendix C: Bioaerosol Run Sheet

Device #:\_\_\_\_\_Run #:\_\_\_\_\_

Date:\_\_\_\_\_

Test Operator:\_\_\_\_\_

Climet Filename:\_\_\_\_\_

### Test Conditions:

Test Flow Rate	ASME Nozzle Pressure Drop	Temperature	RH	Ambient Atm Pressure
CFM	in. H <sub>2</sub> O	°F	%	in. Hg

### Biological Suspension:

Organism:\_\_\_\_\_

Suspension Prep:\_\_\_\_\_

Drying Air:\_\_\_\_\_

Nebulizer Pressure:\_\_\_\_\_

Initial Volume:\_\_\_\_\_

Time On:\_\_\_\_\_

### Biological Sampling:

Sample #	Time Run Begins	Sample Length (min.)	Media
U1, U2, U3			
D1, D2, D3			
D4, D5, D6			
U4, U5, U6			
U7, U8, U9			



D7, D8, D9			
D10, D11, D12			
U10, U11, U12			

$U_i$  = upstream sample  $i$   
 $D_i$  = downstream sample  $i$

Rotometer/Vac #1 Reading: \_\_\_\_\_

Rotometer/Vac #2 Reading: \_\_\_\_\_

Rotometer/Vac #3 Reading: \_\_\_\_\_